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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,389	02/12/2002	Mark A. Scialdone	CL1723 US NA	5572

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EXAMINER	
MAYES, LAURIE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,389	SCIALDONE ET AL.	
	Examiner	Art Unit	
	Laurie Mayes	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☒ Claim(s) 4-6 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4)☐ Interview Summary (PTO-413) Paper No(s) _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification lacks a description which would enable one skilled in the art to make any "peptide" or any "polymer" of claim 5. The applicant may amend claim 5 to include specific peptides or polymers which are enabled in the specification.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language "selected from the group consisting of . . . trachoma, or Osler-Webber-Rendu disease" is improper Markush group language.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language "combinations thereof" is vague and fails to state the specific components of the combinations.

Claim Objections – 37 CFR 1.75(c)

Claims 4-6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel

the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The applicant claims a tripeptide in claim 1. Claims 4-6, which are dependent on claim 1, fail to claim subject matter that narrows the scope of claim 1; rather, they enlarge the scope of claim 1 by claiming a tripeptide which is capped with an additional peptide; a polypeptide is of greater scope than a tripeptide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ernst Malle et al. (Malle, Ernst, Anton Ibovnik, Armin Steinmetz, Gerhard M. Kostner and Wolfgang Sattler. Identification of glycoprotein IIB as the lipoprotein(a)-binding protein on platelets: lipoprotein(a) binding is independent of an Arginyl-Glycyl-Aspartate tripeptide located in apolipoprotein(a). Arteriosclerosis and Thrombosis, Vol. 14, No. 3, March 1994, pp. 345-351.) Malle et al. teach the isolated RDG tripeptide sequence (Figure 7 and p. 349, col. 2, line 13), the RGD as capped in apo(a) (p.349, col. 2, lines 6-7) and a composition containing RGD and l-lipoprotein(a) (Figure 7). Angiogenesis-inhibitory characteristics are inherent in the tripeptide RGD. Therefore, claims 1, 4 and 7 are anticipated by this reference.

Claim Rejections - 35 USC § 102(a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Maeshima, Yohei et al. (Maeshima, Yohei, Pablo C. Colorado, Adrianna Torre, Kathryn A. Holthaus, James A. Grunkemeyer, Mark B. Ericksen, Helmut Hopfer, Yingwen Xiao, Isaac E. Stillman, and Raghu Kalluri, J. Biol. Chem., Vol. 275, Issue 28, pp. 21340-21348). Maeshima teaches that an inhibition of the proliferation of epithelium cells is an angiogenic property and that the tripeptide sequence SNS, is specifically required for the inhibition of the proliferation of epithelium cells which are in turn required for angiogenesis. (col. 1, paragraph 2, p. 21341) Thus, Maeshima teaches that SNS is anti-angiogenic. The SNS tripeptide is found naturally occurring in the alpha 3 chain of Type IV collagen at amino acids 189-191 (col. 1, paragraph, 2, p. 21341) and is capped. Thus, Maeshima teaches all of the elements of claims 1-4 and these claims are anticipated by this reference. Maeshima teaches a collagen composition containing the SNS sequence in an angiogenesis-inhibitory amount and thus claims 7 and 8 are anticipated (p. 21341, col.2, 3rd para.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 4-22 are rejected under 35 U.S.C. 103(a) as being obvious over Buckley (Buckley, Christopher et al. RGD peptides induce apoptosis by direct capsase-3 activation. Nature (397) 11 Feb 1999, pp. 534-539.) in view of Matsuo et al. (United States Patent Number 5,187,156). Buckley teaches that the RGD tripeptide has anti-angiogenic properties (p. 535, lines 14-17); the RGD sequence is contained in a larger protein and is capped (Figure a, p. 536). It is known in the art that a peptide containing the tripeptide RGD may be capped at the amino-terminal with an acetyl group and may be capped at the carboxy-terminal with an amide group[1]. Therefore, Buckley also teaches claims 5 and 6. Buckley, however, does not teach the administering of an effective anti-angiogenic amount of the tripeptide in a pharmaceutically acceptable carrier. Matsuo et al. teach the combining of the tripeptide DTrp-Phe with therapeutic properties, namely, tachykinin antagonism activity, with a pharmaceutically acceptable carrier for therapeutic use in the treatment and prevention of asthma (abstract and col. 1, lines 7-16). The delivery methods cited in claims 16, 17, and 20-22 are known and routine in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to combine the tripeptide RGD with anti-angiogenic properties with a pharmaceutically acceptable carrier and to administer the combination by any well-known delivery method for therapeutic use in the treatment of angiogenesis. Likewise, it would have been obvious to administer the tripeptide and carrier to treat the symptoms of angiogenesis alone and to treat angiogenesis when it occurs concurrently with other diseases. Thus, claims 1 and 4-22 are obvious over Buckley in view of Matsuo et al.

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[1] Blaschuk et al. United States Patent Number 6,169,071 B1 (see column 3, lines 21-25 and column 27, lines 1-5).

Claims 1, 9 and 12-19 are rejected under 35 U.S.C. 103(a) as being obvious over Buckley in view of Wickham et al. (Wickham, Thomas, Edith Tzeng, Larry Shears II, Peter Roelvink, Yuan Li, Gai Lee, Douglas Brough, Alena Lizonova, and Imre Kovesdi. Increased in vitro and in vivo gene transfer by adenovirus vectors containing chimeric fiber proteins. Journal of Virology, Vol. 71, No. 11, Nov. 1997, pp. 8221-8229.) Buckley teaches that the RGD tripeptide sequence has angiogenesis-inhibitory properties. Administering an effective antiangiogenic-amount of the tripeptide to a tissue would be expected, absent evidence to the contrary. Buckley does not teach administering this peptide by encoding nucleic acid and incorporation into a vector, adenovirus or DNA. Wickham teaches a method of incorporation of the RGD angiogenesis-inhibitory peptide sequence into an adenovirus (p. 8221, col. 1, 1st paragraph) and nucleic acids (p. 8222, col. 2, last para.). It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to administer the angiogenesis-inhibitory peptide to tissue via encoding nucleic acid and incorporation into a vector, adenovirus or DNA. Thus, claims 1, 9, 18 and 19 are obvious over Buckley in view of Wickham et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 7 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
November 27, 2002

GABRIELLE BUGAISKY
PRIMARY EXAMINER